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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,864	05/14/2001	Lars Eyde Theill	A-686B	9916

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U.S. Patent Operations/ TJG
Dept. 4300, M/S 27-4-A
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 04/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,864	THEILL ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Sequence Compliance

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

The following CRF error was corrected by STIC: Examined diskette contents, CRF3 error-Reprocessed diskette contents-Diskette contents did not match original sequence entry.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, and 11-13, drawn to a method of inhibiting **B or T cell proliferation or activation** in mammal comprises administering a therapeutic agent comprising a specific partner as it reads on an antibody; classified in Class 424, subclass 141.1.

II. Claims 1, and 14-21, drawn to a method of inhibiting **B or T cell proliferation or activation** in mammal comprises administering a therapeutic agent comprising a specific partner as it reads on a peptide; classified in Class 514, subclass 2.

III. Claims 2, and 11-13, drawn to a method of inhibiting **APRIL activity** in a mammal comprises administering a therapeutic agent comprising a specific binding partner as it reads on an antibody; classified in Class 424, subclass 141.1.

IV. Claims 2, and 14-21, drawn to a method of inhibiting **APRIL activity** in a mammal comprises administering a therapeutic agent comprising a specific binding partner as it reads on a peptide; classified in Class 514, subclass 2.

V. Claims 3-4, and 11-13, drawn to a method of inhibiting TACI **activity, BCMA activity or both** in mammal comprises administering a specific binding partner such as an antibody for APRIL comprises and further comprising administering a specific binding partner such as an antibody for AGP-3; classified in Class 424, subclass 141.1.

VI. Claims 3-4, and 14-24, drawn to a method of inhibiting TACI **activity**, BCMA **activity or both** in mammal comprises administering a specific binding partner as it reads on a peptide for APRIL comprises, wherein the specific binding is a sequence of TACI and further comprising administering a specific binding partner such as a peptide for AGP-3; classified in Class 514, subclass 2.

VII. Claims 3-4 and 25, drawn to a method of inhibiting TACI **activity, BCMA activity or both** in mammal comprises administering a specific binding partner for APRIL as it reads on an a molecule having an antibody sequence in which one or more antibody CDR regions are replaced; classified in Class 424, subclass 133.1.

VIII. Claims 5 and 11-13, drawn to a method of increasing T **cell proliferation** in a mammal comprises administering a therapeutic agent comprising a specific binding partner as it reads on an antibody; classified in Class 424, subclass 141.1.

IX. Claims 5 and 14-21, drawn to a method of increasing T **cell proliferation** in a mammal comprises administering a therapeutic agent comprising a specific binding partner as it reads on a peptide; classified in Class 514, subclass 2.

X. Claims 6 and 11-13, drawn to a method of increasing APRIL **activity** in a mammal comprises administering a therapeutic agent comprising a specific binding partner as it reads on an antibody; classified in Class 424, subclass 141.1.

XI. Claims 6 and 14-21, drawn to a method of increasing APRIL **activity** in a mammal comprises administering a therapeutic agent comprising a specific binding partner as it reads on a peptide; classified in Class 514, subclass 2.

XII. Claims 7 and 23-24, drawn to method of treating **B-cell lymphoproliferative disorders** comprises administering a therapeutic agent comprising an amino acid sequence; Classified in Class 514, subclass 2.

XIII. Claims 7 and 26, drawn to method of treating **B-cell lymphoproliferative disorders** comprises administering a therapeutic agent comprising an amino acid sequence wherein said amino acid sequence replaces a CDR region within an antibody molecule; Classified in Class 424, subclass 133.1.

XIV. Claims 8, and 23-24, drawn to method of treating **T-cell lymphoproliferative disorders** comprises administering a therapeutic agent comprising an amino acid sequence; Classified in Class 514, subclass 2.

XV. Claims 8, and 26, drawn to method of treating **T-cell lymphoproliferative disorders** comprises administering a therapeutic agent comprising an amino acid sequence wherein said amino acid sequence replaces a CDR region within an antibody molecule; Classified in 424, subclass 133.1.

XVI. Claims 9-10 and 23-24, drawn to method of treating **one or more solid tumors** comprises administering a therapeutic agent comprising an amino acid sequence; Classified in Class 514, subclass 2.

XVII. Claims 9-10 and 26, drawn to method of treating **one or more solid tumors** comprises administering a therapeutic agent comprising an amino acid sequence wherein said amino acid sequence replaces a CDR region within an antibody molecule; Classified in Class 424, subclass 133.1.

XVIII. Claims 27-31, drawn to a composition of matter of the formula $(X^1)_a$-F^1-$(X^2)_b$, classified in Class 530, subclass 350.

XIX. Claims 32-37, drawn to an isolated nucleic acid encoding the composition of matter, expression vectors, host cells, classified in Class 536, subclass 23.5; Class 435, subclasses 455, 252.3, and 320.1.

4. Groups XVIII and XIX are different products. Composition of matters comprising amino acids and nucleic acids, differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups I-XVII are different methods. A method of inhibiting, a method of increasing and a method of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups XVIII/ II, XVIII/ IV, XVIII/ VI, XVIII/ IX, XVIII/ XI, XVIII/ XII, XVIII/ XIV and XVIII/ XVI are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition of Group XVIII can be used immunogen to make antibodies, in addition to the methods of inhibiting, increasing and treating recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group I, III, VIII, or X is elected, applicant is required to elect a method for inhibiting B or T cell proliferation, activation or a method of inhibiting APRIL activity, a method of increasing T cell proliferation or a method of increasing APRIL activity comprises administering a therapeutic agent comprising a specific partner wherein the specific partner is antibody for:

(i) TACI, wherein the antibody has TACI antagonist activity;
(ii) BCMA, wherein the antibody has BCMA antagonist activity;
(iii) both (i) and (ii); or
(iv) TACI and BCMA, wherein the antibody has TACI antagonist activity, BCMA antagonist activity or both.

Antibodies to TACI, BCMA or TACI and BCMA are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

B. If Group II, IV, VI, IX, or XI is elected, applicant is required to elect a method for inhibiting B or T cell proliferation or activation or a method of inhibiting APRIL activity, a method of inhibiting TACI activity, BCMA activity or both, a method of increasing T cell proliferation, or a method of increasing APRIL activity comprises administering a therapeutic agent comprising a specific partner wherein the specific partner is a peptide for:

(i) TACI, wherein the peptide has TACI antagonist activity;
(ii) BCMA, wherein the peptide has BCMA antagonist activity;
(iii) both (i) and (ii); or
(iv) (iv)TACI and BCMA, wherein the peptide has TACI antagonist activity, BCMA antagonist activity or both.

Wherein the peptide is comprised within a molecule of the formula: $(X^1)_a$-F^1-$(X^2)_b$, applicant is required to elect a specific structure from the formula, for example in claim 18, the formula F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2, wherein one of P^1 and P^2 is a specific binding partner for TACI and the other is a specific binding partner for BCMA, L^1 same as L^2, c and d are each independently 0 or 1, have the following 8 possiblies:

1. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = TACI, P^2 =BCMA, c=0, d=0,
2. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = TACI, P^2 =BCMA, c=0, d=1,
3. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = TACI, P^2 =BCMA, c=1, d=0,
4. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = TACI, P^2 =BCMA, c=1, d=1,
5. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 =BCMA, P^2 = TACI, c=0, d=0,
6. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = BCMA, P^2 = TACI, c=0, d=1,
7. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = MCMA, P^2 = TACI, c=1, d=0, or
8. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 =BCMA, P^2 = TACI, c=1, d=1.

peptides to TACI, BCMA or TACI and BCMA are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints. Also, different peptide structures are distinct species because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

C. If Group VII is elected, applicant is required to elect a method for inhibiting TACI activity, BCMA activity or both comprises administering a therapeutic agent comprising a specific partner wherein the specific partner is a molecule having an antibody sequence in which one or more antibody CDR regions are replaced by one or more sequences wherein the sequence is:

A.
B. the extracellular region of TACI (SEQ ID NO:15);
C. the extracellular region of BCMA (SEQ ID NO:6);
D. the consensus region of TACI (SEQ ID NO:16);
E. the consensus region of BCMA (SEQ ID NO:7);
F. the TACI/BCMA extracellular consensus region (SEQ ID NO:13);
G. the sequence of a peptide capable of specifically binding APRIL; or
H. the sequence of a peptide capable of specifically binding AGP-3.

different sequences are distinct species because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

D. If Group XII, XIII, XIV, XV, XVI or XVII is elected, applicant is required to elect a method for treating T-cell lymphoproliferative disorders or a method of treating one or more solid tumors comprises administering amino acid sequence wherein the sequence is:

A. the extracellular region of TACI (SEQ ID NO:15);
B. the extracellular region of BCMA (SEQ ID NO:6);
C. the consensus region of TACI (SEQ ID NO:16);
D. the consensus region of BCMA (SEQ ID NO:7); or
E. the TACI/BCMA extracellular consensus region (SEQ ID NO:13).

different sequences are distinct species because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

E. If Group XV or XVI is elected, applicant is required to elect a method for treating one or more solid tumors comprises administering wherein the tumor is:

A) lung,
B) gastrointestinal,
C) pancreatic,
D) prostate
E) any single combination of A through D.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

F. If Group XVIII or XIX is elected, applicant is required to elect a composition of matter or an isolated nucleic acid encoding the composition of matter of the formula, wherein the formula: $(X^1)_a$-F^1-$(X^2)_b$, applicant is required to elect a specific structure from the formula, for example in claim 30, the formula F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein one of P^1 and P^2 is a specific binding partner for TACI and the other is a specific binding partner for BCMA, L^1 and L^2 are the same, c and d are each independently 0 or 1, have the following 8 possiblies:

1. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = TACI, P^2 =BCMA, c=0, d=0,
2. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = TACI, P^2 =BCMA, c=0, d=1,
3. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = TACI, P^2 =BCMA, c=1, d=0,
4. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = TACI, P^2 =BCMA, c=1, d=1,
5. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 =BCMA, P^2 = TACI, c=0, d=0,
6. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = BCMA, P^2 = TACI, c=0, d=1,
7. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 = MCMA, P^2 = TACI, c=1, d=0, or
8. F^1-$(L^1)_c$-P^1-$(L^2)_d$-P^2 wherein P^1 =BCMA, P^2 = TACI, c=1, d=1.

different peptide structures are distinct species because their structures and modes of action are different which, in turn, address different pathological conditions and therapeutic endpoints.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
March 29, 2002

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800 1640